**Medication Delivery**
**Regulatory Affairs**

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June 25, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5230 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Federal Register Notice April 15, 2003 (FR Vol 68, No. 72, Page 18248)**

**Docket No. 01D-0368**

Dear Colleague:

Baxter Healthcare Corporation is submitting comments on the Draft Guidance for Industry entitled "*Submitting Marketing Applications According to the ICH-CTD Format – General Considerations,* " reopened for comment on April 15, 2003. General comments are presented below with reference to the applicable section numbers.

**General Comments:**

1. Baxter appreciates and supports the Agency's recommendations on preparing a CTD for submission to FDA. The draft guidance is applicable to generic products, however does not contain specific information relative to ANDAs. For example, Section III.B, Module 2, is not clear as to its applicability to ANDAs. The table in Appendix B clearly shows Module 2 as not applicable to an ANDA. Specific notations where the guidance does not apply to generic drug products or where requirements for generic product may differ would help to clarify the recommendations.

2. Since the issuance of this draft guidance document in August 2001, new information has become available on FDA's website regarding the recommendations for content and format of Module 1. Section III.A., Module 1, should be updated to be consistent with the agency's current thinking as expressed in the US Regional DTD posted on FDA's website.

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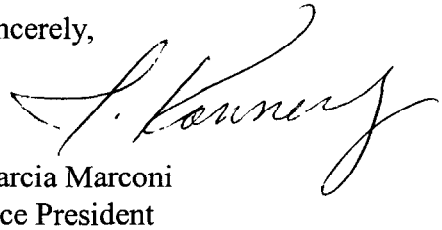
3. Under Section L, Cross referencing documents, it may be difficult to include the volume number, tab identifier and page number with each cross reference. In most cases this information is not available early enough in the submission process to be referenced throughout the document. Providing the CTD module and section number with each cross reference should be adequate.

4. The table in Appendix B, under the ANDA requirements column, is inconsistent with the US Regional DTD for Module 1. This table lists the waiver of in vivo bioavailability/bioequivalence in Module 5, which is contained in Module 1 in the Regional DTD.

Baxter appreciates the opportunity to comment on this important draft guidance. If you have any questions regarding our comments, please contact Judy Kannenberg or myself at (847) 270-2577.

Sincerely,



for Marcia Marconi
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